UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.*
TERESA ROSS,

Plaintiff,

v.

DECISION AND ORDER
12-CV-299S

INDEPENDENT HEALTH CORPORATION,
DxID LLC,
BETSY GAFFNEY, and
INDEPENDENT HEALTH ASSOCIATION, INC.,

Defendants.

I. INTRODUCTION

In this False Claims Act case, the government alleges through its 102-page Complaint-in-Intervention that Defendants defrauded the federal Medicare program by submitting false and inflated claims for reimbursement. Defendants have jointly moved to dismiss the Complaint for failure to state a claim upon which relief can be granted. For the reasons that follow, Defendants' motion is granted in part and denied in part, and the government is granted leave to file a First Amended Complaint-In-Intervention.

II. BACKGROUND[1]

Relator Teresa Ross commenced this action on behalf of the United States in April 2012, alleging violations of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729, et seq. (Docket No. 1). In August 2021, after nearly a decade of investigation, this Court permitted the government to intervene after the government previously declined to do so.

[1] The facts are taken from the Complaint and treated as true for the purposes of this motion. See Cornelio v. Connecticut, 32 F.4th 160, 168 (2d Cir. 2022).

See U.S. *ex rel.* Ross v. Indep. Health Corp., et al., 12-CV-299S, 2021 WL 3492917 (W.D.N.Y. Aug. 9, 2021). The government filed its Complaint-in-Intervention ("Complaint") on September 13, 2021, seeking damages under the FCA and restitution under common law (Complaint, Docket No. 142). Defendants moved to dismiss on November 16, 2021, with briefing, including supplemental briefing, concluded on November 30, 2022, at which time this Court reserved decision without oral argument (Docket Nos. 154, 156-160).

A. Parties

Relator Ross is the former Director of Risk Adjustment Services for Group Health Cooperative ("GHC"), a private insurer (and former defendant[2]) that offered a Medicare Advantage Plan (Complaint at ¶ 24). Before becoming director of that division, Ross was GHC's Director of Insurance and Health Data Analysis, a position in which she implemented the standard risk-adjustment claims-verification procedures and developed algorithms to identify and correct diagnosis-coding issues to ensure accurate and complete risk-adjustment claims submissions (id.). As part of her employment, Ross became familiar with the Medicare risk-adjustment system and Defendant DxID LLC's ("DxID") alleged misconduct at GHC (id.).

Defendant Betsy Gaffney founded Defendant DxID and served as its CEO (id. at ¶ 28). Before founding DxID, Gaffney was a principal at non-party Cognisight (id.). Cognisight and DxID provided risk-adjustment and chart-review services to insurers who offered Medicare Advantage Plans (id. at ¶ 28).

DxID is a subsidiary of Defendant Independent Health Corporation ("IHC"), which

[2] Group Health Cooperative settled the claims against it for $6,375,000 (Docket Nos. 125, 135).

is a for-profit subsidiary of Defendant Independent Health Association, Inc. ("IHA") (collectively "IH"), a non-profit corporation that offers Medicare Advantage Plans in New York (id. at ¶¶ 25-27).

B. Medicare Part C

Medicare is a federally operated health insurance program administered by the Centers for Medicare & Medicaid Services ("CMS") for individuals aged 65 and older and the disabled (Complaint at ¶ 41). Medicare Parts A and B—sometimes referred to as "traditional" Medicare—are fee-for-service programs in which providers submit claims to CMS for healthcare services actually rendered, with CMS paying providers directly for each service based on rates predetermined by the government (id. at ¶ 42). In other words, Parts A and B are reimbursement programs. Part A covers inpatient and institutional care; Part B covers physician, hospital, outpatient, and ancillary services and durable medical equipment (id.).

Medicare Part C, which is at issue here, is not a traditional reimbursement program. Part C allows beneficiaries to receive their healthcare services through Medicare Advantage ("MA") Plans managed by private insurers known as MA Organizations ("MAOs") (id. at 43). MAOs contract with CMS to provide healthcare services (id. at ¶ 44), and in turn, CMS pays MAOs on a per-member, per-month or capitated basis (id. at ¶ 3). But unlike Parts A and B, payments under Medicare Part C do not directly correlate to the healthcare services actually provided, but rather, consist of a fixed amount for each beneficiary based on that beneficiary's expected average cost of care (id. at ¶ 64). This payment is adjusted among individual beneficiaries for risk factors that affect healthcare costs, such as age, disability status, gender, and institutional

status (id. at ¶¶ 64-66). Part C thus employs a risk-adjustment (rather than reimbursement) model for payment (id. at ¶ 65).

Under the risk-adjustment system, CMS pays more for members in poor health and for members who have conditions that are costlier to manage than for healthier members (id.). Diagnosis codes that correlate to medical conditions are used to document the state of each member's health (id.). These codes are generated by health care providers based on their encounters (e.g., office visits) with members (id. at ¶¶ 71-77). MAOs then transmit these codes to CMS for payment. Diagnosis codes thus directly affect the payments MAOs receive from CMS (id. ¶¶ 3, 4, 89).

The Department of Health and Human Services has adopted the International Classification of Diseases Guidelines for Coding and Reporting (the "ICD Guidelines") as the standard for medical documentation, including the identification of diagnosis codes for health conditions. See 45 C.F.R. §§ 162.1002 (a)(1)(i), (b)(1), (c)(2), and (c)(3); Complaint at ¶¶ 72, 74. These Guidelines direct MAOs to, *inter alia*, "[c]ode all documented conditions that coexist at the time of the encounter/visit, and require or affect patient care, treatment or management" (Complaint at ¶ 76). This is the standard principally at issue here.

C. Alleged Fraud

The government alleges that Defendants fraudulently collected and retained higher payments from CMS than they were entitled to by overstating members' health conditions through the submission of inaccurate and unsupported diagnosis codes, which violated both the CMS regulations and Defendants' contractual obligations to CMS (Complaint at ¶¶ 2, 5, 6, 91-93, 127). To execute this scheme, IH created DxID to, among

other things, manage chart review and monitor medical coding (id. at ¶¶ 6, 95, 120, 121, 126).

Under Gaffney's leadership, DxID offered two services that "captured" diagnosis codes for MAOs, like IH, to submit to CMS to receive higher monthly payments for providing insurance to enrollees (id. at ¶¶ 5, 7, 17, 94). These services were (1) a retrospective chart-review program, which consisted of a re-review of enrollees' medical records for additional diagnosis codes (id. at ¶¶ 12, 112); and (2) an addenda process that "nudged" medical providers to retroactively add diagnoses to medical records (id. at ¶¶ 15-17, 94, 113). The government alleges that these services were designed to capture and cause the submission of diagnosis codes that were inaccurate and inadequately documented in medical records, with Defendants sharing millions of dollars in increased payments (id. at ¶¶ 6, 7, 9, 21, 92, 128, 129, 134).

The general scheme to defraud, including the fraud at GHC, is set out in paragraphs 129-412 of the Complaint. In brief, the government alleges that DxID's chart-review program relied on "trolling" patient medical records to "gin up" diagnoses, derived in many cases from sources like Problem Lists, Past Medical History, labs (e.g. diagnostic and radiology tests), and orders for Durable Medical Equipment ("DME"), such as oxygen (id. at ¶ 142). This resulted in the capture of diagnosis codes that were not documented by qualified providers; that did not exist at the time of the encounter or visit; that did not require or affect patient care, treatment, or management; and that were otherwise not supported by the medical records (id. at ¶¶ 141, 284).

At IH, DxID mined patient records for any indication of risk-adjusting conditions, even if those indications were from years before or noted by other providers (id. at ¶ 286).

If DxID found something approximating a risk-adjusting condition, it would code the condition based on the assumption that the old, or even automated record, was available to the enrollee's provider during an encounter (id.). Defendants would combine this older information with unrelated encounters that occurred during the relevant service year to code the condition and claim that it required or affected patient care, treatment, or management (id. at ¶ 284). At other times, Defendants captured diagnosis codes that were not even mentioned in prior years based on an assumption that the conditions were common among senior citizens (id. at ¶ 287).

The addenda process complemented the retrospective chart-review program (id. at ¶¶ 339, 340, 355). DxID specifically crafted its addenda process to capture lucrative risk-adjustment diagnoses to increase payments from CMS (id. at ¶ 345.) DxID first analyzed a medical record using data analytics to identify whether there was a potential marker of conditions with high risk-adjustment reimbursement rates that had not been recorded by treating physicians (id. at ¶ 346). After identifying such a record, DxID "queried" the patient's provider using a medical record addendum ("MRA") form (id. at ¶ 347). These forms were often sent to the provider many months and even up to a year after the patient encounter for which the addendum would serve as a supplement (id.). The MRA form offered a list of conditions for the provider to check off (id. at ¶ 348). DxID did not know if the condition existed at the time of the visit but added the conditions to the MRA forms based on analytics or simply because they were valuable diagnoses (id.). DxID paid providers $25 per completed MRA form (id. at ¶ 349). If a provider did not complete the MRA form on his or her own, DxID employees, with permission from IH, went to the provider's medical office, reviewed the beneficiary's medical records, checked

off diagnoses on the MRA forms, and presented a pre-filled form to the provider to sign (id. at ¶ 351).

Gaffney has stated that providers took 2-3 minutes to complete each MRA form (id. at ¶ 352(c)). She noted that the MRA forms generally had more than one diagnosis listed, and some would—while others would not—be correct (id. at ¶¶ 353 (b), 369). DxID and IH knew or recklessly disregarded that the diagnosis codes captured and submitted because of this addenda process often did not coexist at the time of the patient encounter or were not documented during the year of service as requiring or affecting patient care, treatment, or management (id. at ¶ 370).

IH was concerned about the addenda process such that it stopped using DxID for a few months in 2015 (id. at ¶ 378). But IH restarted the chart-review program and resumed the addenda process in 2016 (id.).

III. DISCUSSION

The government asserts seven causes of action against Defendants. The first five fall under the FCA. First, the government alleges that Defendants knowingly presented false or fraudulent claims for payment or approval resulting in inflated CMS reimbursements to which they were not entitled (Complaint at ¶¶ 413-416). Second, the government alleges that Defendants knowingly made and used false records and statements material to false or fraudulent claims resulting in inflated reimbursements (id. at ¶¶ 417-420). Third, the government alleges that Defendants knowingly made and used false records and statements material to an obligation to pay or transmit money or property to the government by creating false records and making false statements relating to their failure to delete codes for unsupported diagnoses or to repay CMS overpayments

to which they were not entitled (id. at ¶¶ 421-424). Fourth, the government alleges that Defendants knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the government by failing to delete codes for unsupported diagnoses or otherwise repay CMS for overpayments (id. at ¶¶ 425-428). Fifth, the government alleges that Defendants conspired to violate the FCA by submitting unsupported codes for reimbursement (id. at ¶¶ 429-432).

The government's final two claims are common law causes of action. In its sixth claim, the government alleges that CMS paid monies to Defendants directly or indirectly as a result of its mistaken understanding that Defendants had submitted valid claims based on valid risk-adjustment diagnoses (id. at ¶¶ 433-435). In its seventh claim, the government alleges that Defendants were unjustly enriched at the expense of the United States by engaging in the conduct alleged throughout the Complaint (id. at ¶¶ 436-438).

Defendants move to dismiss each cause of action for failure to state a claim upon which relief can be granted.

A. Motion to Dismiss Standard

Defendants move to dismiss the Complaint under Rule 12 (b)(6) of the Federal Rules of Civil Procedure. Rule 12 (b)(6) allows dismissal of a complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12 (b)(6). The rule is "designed to test the legal sufficiency of the complaint, and thus does not require the Court to examine the evidence at issue." DeJesus v. Sears, Roebuck & Co., 87 F.3d 65, 69 (2d Cir. 1996). The question, rather, is whether the complaint meets the applicable pleading standards. See Berry v. Tremblay, 9:20-CV-177 (DNH/TWD), 2021 WL 1575951, at *2 (N.D.N.Y. Apr. 22, 2021) ("The [Rule 12 (b)(6)] motion tests the legal

sufficiency of the complaint and whether it conforms to Rule 8 (a)(2) of the Federal Rules of Civil Procedure.").

Federal pleading standards are generally not stringent: Rule 8 requires only a short and plain statement of a claim. Fed. R. Civ. P. 8 (a)(2). But the plain statement must "possess enough heft to show that the pleader is entitled to relief." Bell Atl. Corp. v. Twombly, 550 U.S. 554, 557, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007). When determining whether a complaint states a claim, the court must construe it liberally, accept all factual allegations as true, and draw all reasonable inferences in the plaintiff's favor. See ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 98 (2d Cir. 2007). Legal conclusions, however, are not afforded the same presumption of truthfulness. See Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) ("the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions").

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Iqbal, 556 U.S. at 678 (quoting Twombly, 550 U.S. at 570). Labels, conclusions, or "a formulaic recitation of the elements of a cause of action will not do." Twombly, 550 U.S. at 555. Facial plausibility exists when the facts alleged allow for a reasonable inference that the defendant is liable for the misconduct charged. Iqbal, 556 U.S. at 678. The plausibility standard is not, however, a probability requirement: the well-pleaded allegations in the complaint need only nudge the claim "across the line from conceivable to plausible." Twombly, 550 U.S. at 570.

A two-pronged approach is thus used to examine the sufficiency of a complaint. This examination is context specific and requires the court to draw on its judicial experience and common sense. See Iqbal, 556 U.S. at 679. First, statements that are not entitled to the presumption of truth, such as conclusory allegations, labels, and legal conclusions, are identified and stripped away. See id. Second, well-pleaded, non-conclusory factual allegations are presumed true and examined to determine whether they "plausibly give rise to an entitlement to relief." Id. "Where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct," the complaint fails to state a claim. Id.

In considering a motion to dismiss under Rule 12 (b)(6), "a district court must confine its consideration to facts stated on the face of the complaint, in documents appended to the complaint or incorporated in the complaint by reference, and to matters of which judicial notice may be taken." Leonard F. v. Isr. Disc. Bank of N.Y., 199 F.3d 99, 107 (2d Cir. 1999) (quotation marks omitted); see also Blue Tree Hotels Inv. (Can.), Ltd. v. Starwood Hotels & Resorts Worldwide, Inc., 369 F.3d 212, 217 (2d Cir. 2004). "[W]here a document is not incorporated by reference, the court may nevertheless consider it where the complaint relies heavily upon its terms and effect," thereby rendering the document "integral to the complaint." Mangiafico v. Blumenthal, 471 F.3d 391, 398 (2d Cir. 2006) (citing Chambers v. Time Warner, Inc., 282 F.3d 147, 152–53 (2d Cir. 2002)). But even where a document is "integral" to the complaint, it cannot serve as the basis for

dismissal unless there is no dispute as to its authenticity, accuracy, and relevance.[3] See Faulkner v. Beer, 463 F.3d 130, 134 (2d Cir. 2006) (internal citations omitted).

B. False Claims Act (Claims 1-5)

1. Legal Standard

Enacted in 1863, the FCA imposes civil liability upon persons who, *inter alia*, knowingly present or cause to be presented false or fraudulent claims for payment or approval to officers or employees of the United States. See 31 U.S.C. § 3729 (a)(1)(A); see also Vt. Agency of Nat. Res. v. United States *ex rel.* Stevens, 529 U.S. 765, 769, 120 S. Ct. 1858, 1860, 146 L. Ed. 2d 836 (2000). It was enacted "with the principal goal of 'stopping the massive frauds perpetrated by large [private] contractors during the Civil War.'" Vt. Agency, 529 U.S. at 781 (quoting United States v. Bornstein, 423 U.S. 303, 309, 96 S. Ct. 523, 46 L. Ed. 2d 514 (1976)); see also United States v. Sakura Glob. Cap. Mkts., Inc., 377 F.3d 145, 151-52 (2d Cir. 2004); United States *ex rel.* Mikes v. Straus, 274 F.3d 687, 692 (2d Cir. 2001)(explaining that the False Claims Act was enacted "after disclosure of widespread fraud during the War-Between-The-States revealed that the union government had been billed for nonexistent or worthless goods, had been charged exorbitant prices, and had its treasure plundered by profiteering defense contractors") (citing United States v. McNinch, 356 U.S. 595, 599, 78 S. Ct. 950, 2 L. Ed. 2d 1001

[3]Defendants attach numerous documents to their motion, which they argue are either subject to judicial notice (see Docket No. 154-1, p. 16 & n.3) or referred to in the Complaint (see, e.g., Docket No. 154-2, ¶ 9), such that consideration of the materials is appropriate without the need to convert the motion to one for summary judgment. This Court has discretion "to determine whether or not to accept the submission of any material beyond the pleadings that is offered in conjunction with a Rule 12 (b)(6) motion and rely on it, thereby converting the motion, or to reject it or simply not consider it," 5C Charles A. Wright & Arthur R. Miller, Federal Practice and Procedure § 1366, at 159 (3d ed. 2004). At this stage, this Court finds it unnecessary to reach the materials accompanying Defendants' motion or to convert the motion to one for summary judgment.

(1958)); cf. S. Rep. No. 345, at 1 (1986), as reprinted in 1986 U.S.C.C.A.N 5266, 5266 (describing the purpose of the False Claims Act as "to enhance the Government's ability to recover losses sustained as a result of fraud against the Government").

"The False Claims Act imposes liability, as relevant here, on a person who either 'knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,' or who 'knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim'" made to the government. United States v. Strock, 982 F.3d 51, 58 (2d Cir. 2020) (quoting 31 U.S.C. § 3729(a)(1)(A)-(B)). An FCA claim therefore requires falsity and knowledge.

As to falsity, "[a] successful FCA claim generally occurs in one of three forms: (1) a factually false claim; (2) a legally false claim under an express false certification theory; and (3) a legally false claim under an implied certification theory." United States ex rel. Foreman v. AECOM, 19 F.4th 85, 104 & n.7 (2d Cir. 2021) (internal quotation marks and citations omitted), cert. denied, No. 21-1314, 2022 WL 1295727 (2022). A factually false claim involves a claim that "is untrue on its face." Id. (internal quotation marks and citation omitted).

In contrast, the latter two types of FCA claims allege legal falsity. That is, they "do not involve information that is false on its own terms, but instead rest on a false representation of compliance with an applicable federal statute, federal regulation, or contractual term." Id. (internal quotation marks and citation omitted). "An express false certification occurs when a claimant explicitly represents that he or she has complied with [such] a . . . condition, but in fact has not complied." Id. And an implied false certification claim "arises where the defendant submits a claim for payment, impliedly certifying

compliance with conditions of payment while omitting its violations of statutory, regulatory, or contractual requirements, and these omissions render the representations misleading." Id.

As to knowledge, a plaintiff must establish that the defendants presented a materially false claim either "with 'actual knowledge of the information,' 'in deliberate ignorance of the truth or falsity of the information,' or 'in reckless disregard of the truth or falsity of the information.'" Strock, 982 F.3d at 66 (quoting 31 U.S.C. § 3729(a)(1)(A)-(B)).

In legally false FCA claims—that is, claims based on a false representation of compliance with an applicable federal statute, regulation, or contractual term—"a defendant cannot act 'knowingly' if it bases its actions on an objectively reasonable interpretation of the relevant statute[, regulation, or contractual provision] when it has not been warned away from that interpretation by authoritative guidance." United States ex rel. Sheldon v. Allergan Sales, LLC, 24 F.4th 340, 348 (4th Cir. 2022); see also United States ex rel. Johnson v. Golden Gate Nat'l Senior Care, L.L.C., 223 F. Supp. 3d 882, 891 (D. Minn. 2016) ("In short, if a regulation is ambiguous, a defendant may escape liability if its interpretation of the regulation was reasonable in light of available official guidance—even if the interpretation was 'opportunistic.'").

2. The government sufficiently alleges the violation of a legal obligation.

Defendants first argue that dismissal is required because the government has failed to allege a violation of an enforceable legal obligation. Casting the Complaint as seeking to enforce coding policies that do not exist, Defendants maintain that the micro-level "purported coding rules" described by the government do not support FCA liability.

The government maintains in response that the Complaint sufficiently alleges that Defendants violated their legal obligations under both applicable federal regulations and the MA contracts.[4]

Having thoroughly reviewed the Complaint, this Court finds that it sufficiently alleges the violation of multiple legal obligations. At the outset, there is no dispute that federal regulations require the submission of accurate, complete, and truthful data in support of a claim for payment. See 42 C.F.R. § 422.504 (l). And here the government alleges that Defendants engaged in practices that led to the submission of claims that violated this legal obligation (see Complaint at ¶¶ 51-61, 281-412).

Moreover, federal regulations require compliance with national standards for medical-record documentation, which standards are those contained in the relevant ICD Guidelines.[5] See 42 C.F.R. § 422.310 (d)(1) (requiring MAOs to submit data that conforms, *inter alia*, "to all relevant national standards"); 45 C.F.R. § 162.1002 (a)(1)(i), (b)(1), (c)(2)-(3) (adopting ICD Guidelines as the national standard).

Relevant here is the ICD Guideline pertaining to coding documented conditions:

> **Code all documented conditions that coexist**
> Code all documented conditions that coexist at the time of the encounter/visit, and require or affect patient care treatment or management. Do not code conditions that were previously treated and no longer exist. However, history codes [as specified] may be used as secondary codes if the historical

[4] The MA contracts obligate Defendants to comply with not only all applicable federal statutes, regulations, and policies, but also "all applicable requirements as described in CMS regulations and guidance implementing the Medicare Improvements for Patients and Providers Act of 2008" (Complaint at ¶¶ 47, 55, 56, 58-60, 63).

[5] The relevant guidelines are the 2011 ICD-9-CM Official Guidelines for Coding and Reporting, available at https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf, and the 2014 ICD-10-CM Official Guidelines for Coding and Reporting, available at https://www.cdc.gov/nchs/data/icd/icd10cm_guidelines_2014.pdf. The coding provision at issue is materially the same in each document.

> condition or family history has an impact on current care or influences treatment.

The government alleges that Defendants failed to comply with this obligation, which led to the submission of false claims (see Complaint at ¶¶ 72-77, 281-338). And Defendants readily concede that ICD Guidelines carry the force of law (see Memorandum of Law, Docket No. 154-1, pp. 6, 14).

Nonetheless, Defendants argue that dismissal is warranted because the government misreads this provision as requiring too exacting a standard. They challenge the government's allegation that this ICD guideline requires that "[a] condition must be documented in the medical record as relevant to patient care during an encounter in the DOS year, and not merely mentioned, suggested, or inferred anywhere from records from years past" (Complaint at ¶¶ 13, 77). In Defendants' view, the word "documented" in the first sentence of the guideline modifies only "conditions," and coders are therefore able to infer on their own, without documentation, whether a condition requires or affects a patient's care, treatment, or management. In other words, Defendants argue that the guideline requires only that the *condition* be documented in a medical record, with nothing further required to support a conclusion that the condition coexists at the time of the encounter and requires or affects patient care treatment or management.

This Court's reading of the guideline at this stage finds no support for Defendants' position. While the first sentence is no model of clarity—it erroneously contains a comma setting off the second part of the compound predicate—the provision does not support Defendants' no-further-documentation-required interpretation. Rather, the provision is most naturally read as restrictively defining a subset of documented conditions that may be coded. That subset consists of documented conditions that have two attributes: (1)

they "coexist at the time of the encounter/visit," and (2) they "require or affect patient care treatment or management."

Determining whether a documented condition meets the guideline thus involves a fact-driven inquiry. And consistent with the data-integrity policies that safeguard the Part C program, see, e.g., Unitedhealthcare Ins. Co. v. Becerra, 9 F.4th 868, 877-880 (D.D.C. 2021) (discussing various data-integrity provisions), it follows that such findings must be grounded in some identifiable information or documentation. While the level of documentation may not be specifically set forth in the guideline, it is equally true that the guideline cannot be read at this stage as permitting the necessary findings to be grounded solely in a coder's surmise. Yet by the same token, nothing on the face of the guideline requires that the necessary findings be based on specific documentation by a medical professional either, as the government may be understood to suggest. Thus, a coder's judgment based on some level of supporting information may well meet the guideline.[6]

Understanding the guideline in this manner at this stage, this Court finds that the Complaint sufficiently alleges plausible claims that Defendants violated their legal obligations. The government generally alleges that Defendants violated the guideline by submitting codes for conditions that did not fall into the permitted subset, whether because the conditions were not sufficiently documented, did not coexist at the time of encounter, or did not require or affect patient treatment or management (see, e.g., Complaint at ¶ 13 (generally alleging that Defendants disregarded the requirement that a

[6] This Court is not moved by Defendants' reliance on United States *ex rel.* Rasmussen v. Essence Group Holdings Corp., as that case is non-precedential and not explicitly focused on interpreting the language at issue here. No. 17-3273-CV-S-BP, 2020 WL 438177, at *7 (W.D. Mo. Apr. 29, 2020).

condition must be relevant to patient care, treatment, or management during an encounter in the date of service year)).

More specifically, the government alleges that Defendants submitted false claims when they (1) coded exclusively from Problem Lists and Past Medical History, which can be "unrelated to any patient care, treatment, or management during an encounter in the relevant DOS year" (id. at ¶¶ 145, 147, 154, 189-192, 273-276, 284, 286, 288-326); (2) coded conditions like old myocardial infarction ("Old MI") that occurred years ago (id. at ¶¶ 158, 327-330); (3) coded chronic conditions in the absence of documented intervention or further evaluation (id. at ¶¶ 159, 163, 164, 306), (4) coded from reports that were simply *assumed* to be available during a DOS year encounter (id. at ¶¶ 162-165, 221, 286, 306, 328-330); and (5) coded based on unsupported inferences and assumptions (id. at ¶¶ 168-169, 198, 206, 210, 219, 286, 287, 331-338). Moreover, the government alleges that Defendants deliberately designed their addenda process to create false documentation to support diagnosis codes that they knew were inaccurate and false (id. at ¶¶ 339-412). These practices, alleges the government, individually and in combination, resulted in the submission of false claims violative of the national standards.

Consequently, in addition to alleging that Defendants violated their legal and contractual obligations to submit accurate, complete, and truthful data in support of their claims for payment, see 42 C.F.R. § 422.504 (l), the government also plausibly alleges that Defendants violated their legal and contractual obligations to submit data in conformity with all relevant national standards, to wit: the ICD Guidelines. See 42 C.F.R.

§ 422.310 (d)(1); 45 C.F.R. § 162.1002 (a)(1)(i), (b)(1), (c)(2)-(3). The government has therefore sufficiently alleged the violation of a legal obligation.[7]

3. Whether Defendants' coding and addenda policies are consistent with their legal obligations or agency guidance requires a factual inquiry that is precluded at this stage.

Defendants next argue that dismissal is required because their coding and addenda policies were consistent with informal coding guidance provided by CMS and private entities. They maintain that their coding policies complied with the CMS Participant Training Guide, the CMS Risk Adjustment Data Validation ("RADV") protocols, and American Academy of Professional Coders ("AAPC") standards. They maintain that the coding guidance contained in these sources is directly contrary to the government's position in this litigation and instead supports their policies and practices, including permitting coders to make reasonable judgments in the absence of documentation. Defendants thus contend that their alleged policies on coding from Problem Lists, past medical history, incidental findings of artherosclerosis, Old MI from EKGs and chronic kidney disease from laboratory results, and hypoxia were all permissible and consistent with governing guidance. As for its addenda process, Defendants argue that there is no merit to the government's claim that the timing and allegedly leading nature of the addenda resulted in fraudulent claims.

The government strongly disagrees. It maintains that Defendants' claims of compliance are self-serving and impermissibly grounded in inferences drawn in their

[7] Because this Court finds that the Complaint sufficiently alleges violations of Defendants' legal and contractual obligations, it need not reach Defendants' arguments concerning whether violations of sub-regulatory guidance alone can give rise to FCA liability, such as those arguments under Azar v. Allina Health Servs., __ U.S. __, 139 S. Ct. 1804, 204 L. Ed. 2d 804 (2019) and Kisor v. Wilkie, __ U.S. __, 139 S. Ct. 2400, 204 L. Ed. 2d 841 (2019).

favor, and in any event, are not relevant at this stage, where the only issue is whether the government has alleged plausible claims. The government further maintains that Defendants' interpretation of extrinsic coding guidance is incomplete and due no deference in the face of the Complaint's contrary allegations.

Having considered the arguments, this Court concurs in the government's position. As an initial matter, it is correct that Defendants' arguments largely rely on favorable readings of guidance and factual inferences drawn in their favor, each of which is precluded at this stage. See, e.g., Anderson News, L.L.C. v. Am. Media, Inc., 680 F.3d 162, 185 (2d Cir. 2012) ("The choice between two plausible inferences that may be drawn from factual allegations is not a choice to be made by the court on a Rule 12 (b)(6) motion."). Defendants' routinely cite their "reasonable" actions and interpretations, but reasonableness in this context cannot properly be determined at the pleading stage. This is particularly true here, where the government's allegations directly contradict Defendants' claims of compliance.

For example, the government alleges that DxID's practice and policy was to code diagnoses from Problem Lists, which are "used within health records to list illnesses, injuries, conditions, and other factors that *could* affect the health of an individual patient. [Problem Lists] can include old or prior conditions, new conditions based on current symptoms or drugs taken, predicted conditions based on prescription drugs or health status, or suggested conditions from computer algorithms, among others. Problem Lists are often auto-generated or auto-populated" (Complaint at ¶ 147). Despite the allegation—taken as true—that enrollees do not necessarily have the conditions listed in a Problem List (see id. at ¶ 148 (asserting that a condition listed on a Problem List "is not

an *actual* diagnosis")), it was nonetheless DxID's policy to code conditions noted exclusively on the Problem List "without regard for the condition's origin on the Problem List [and] the process for adding conditions to the Problem List" (see id. at ¶¶ 142, 149).

The government alleges that this policy resulted in the submission of diagnosis codes for conditions that were not present. For example, the government alleges that DxID caused GHC to submit a code for major depressive disorder, coded by DxID, based on a Problem List including major depressive disorder, even though the physician's assessment was that the patient's depression was transient and had resolved (id. at ¶¶ 189-90). And DxID is alleged to have used this same practice in its work for IH (id. at ¶¶ 281-304, 304 (d)).

By way of further example, the government alleges that DxID's policy to code an Old MI—which again refers to an old heart attack (id. at ¶ 156)—based solely on electrocardiograms ("EKGs") resulted in high rates of false positive coding of Old MI. Specifically, the government alleges that GHC clinicians reviewed the records of GHC patients who were coded as having Old MI and found that a significant number of them did not in fact have the condition (see id. at ¶¶ 271, 273, 274). Nevertheless, GHC continued to submit the codes to CMS (see id. ¶ 275). The Complaint also alleges that IH submitted Old MI codes pursuant to the same policy, which suggests that IH likewise submitted false Old MI codes (id. at ¶¶ 164, 330). Therefore, the Complaint plausibly alleges that DxID's policy to code Old MI based solely on EKGs resulted in the submission of Old MI codes that were false.

Additionally, the government alleges that DxID's policy was to code chronic conditions found in a record's "Past Medical History" section. The government alleges

that this was improper for various reasons, including that it resulted, at least in one instance for GHC, in the coding of conditions that were resolved (see id. at ¶ 230). IH also submitted codes based on Past Medical History alone (see id. at ¶ 304). See United States ex rel. Silingo v. WellPoint, Inc., 904 F.3d 667, 678–79 (9th Cir. 2018) ("When alleging a scheme to submit false claims, a plaintiff must provide reliable indicia that lead to a strong inference that claims were actually submitted. We do not require the complaint to identify representative examples of actual false claims, though that is one way to satisfy the heightened pleading requirement." (internal quotation marks and citation omitted)).

Moreover, because the Complaint alleges that these practices of coding conditions solely from Problem Lists, EKGs, and Past Medical History resulted in Defendants knowingly submitting inaccurate diagnosis codes, it sufficiently alleges not only factually false claims, but express false-certification claims as well. Medicare regulations require that MAOs certify that their data submissions to CMS are, to the best of their knowledge, information, and belief, accurate, complete, and truthful. See 42 C.F.R. § 422.504(l). Likewise, any related entity, contractor, or subcontractor of the MAO that generates the data must also certify the accuracy, completeness, and truthfulness of the data. Id. § 422.504(l)(3). If an entity knows that its data is false or acts with deliberate indifference or reckless disregard to its falsity, the entity "can no longer certify, based on the best knowledge, information and belief, the accuracy, completeness and truthfulness of the data submitted to CMS." United States v. United Healthcare Ins. Co., 848 F.3d 1161, 1175 (9th Cir. 2016).

Thus, if, as the government alleges, Defendants knew that codes it submitted did not reflect enrollees' conditions, or if they knew that the data was questionable, their

accompanying certification may have been false, thereby giving rise to a plausible express false certification claim. In other words, assuming the truth of the above allegations, Defendants could not have certified to the best of their knowledge, information, and belief that the data submitted was accurate, complete, and truthful. Therefore the Complaint—insofar as it alleges that Defendants' practices resulted in the knowing submission of inaccurate diagnosis codes—states both factually false and express false-certification FCA claims.

The government further alleges that DxID's addendum practice, and IH's submission of codes based on addenda, resulted in the submission of factually false and legally false claims. The government alleges that DxID would analyze an enrollee's medical record to identify whether "there was a potential marker of conditions with high risk adjustment reimbursement rates that had not been recorded by the treating physician" and then query the provider using a medical record addenda form that offered a list of conditions for the provider to check off (Complaint at ¶¶ 346-48).

While this practice may not necessarily be suspect on its face, the government further alleges that despite knowing that a patient did not have a condition (id. at ¶ 369), DxID would include the condition on the form simply because it was valuable to submit to CMS (id. at ¶ 348). Although it was incumbent on the provider to mark that the condition was in fact present, Defendants are alleged to have known that providers would generally take only 2-3 minutes to complete the form (id. at ¶ 375) and would generally accept DxID's representation that the conditions existed (id. at ¶¶ 372, 374). Gaffney was also allegedly aware that providers did not "really read all the information [DxID sent] them regarding the forms" (id. at ¶ 372). And IH was aware that providers would "most times

try to remember by memory if their patients [had the] conditions or not" (id. at ¶ 373). Furthermore, the government alleges that the addenda were sent to providers months after the date of service (id. at ¶ 383), adding to the likelihood of false inclusions. As to specific codes submitted as a result of the addenda practice, the government alleges that DxID and IH knew that the diagnosis codes captured and submitted through the addenda process often did not coexist at the time of the patient encounter in the relevant year (id. at ¶ 370).

Considering these allegations in the aggregate, this Court concludes that the government adequately alleges at least three legal theories based on the addenda practice. First, the government alleges a scheme in which codes were submitted for conditions that enrollees did not have. See Silingo, 904 F.3d at 678-79. Second, these allegations give rise to claims that the addenda forms DxID created were false records or statements. See 31 U.S.C. § 3729(a)(1)(b) (prohibiting the known creation of false records material to a false claim); see also United States ex rel. Riley v. St. Luke's Episcopal Hosp., 355 F.3d 370, 379 (5th Cir. 2004) ("'False' can mean 'deceitful,' or 'tending to mislead.'"). Third, the allegations suggest that Defendants would not be able to attest that diagnosis codes derived solely from the addenda forms were—to the best of their knowledge, information, and belief—accurate, complete, and truthful. See United States ex rel. Ormsby v. Sutter Health, 444 F. Supp. 3d 1010, 1083 (N.D. Cal. 2020). Therefore, the addenda process also gives rise to express certification claims.

Consequently, this Court finds that Defendants' contention that their coding and addenda policies were consistent with their legal obligations or agency guidance is not

grounds for dismissal at this stage, particularly in light of the government's contrary allegations.

4. Whether Defendants' conduct was consistent with an objectively reasonable interpretation of the applicable requirements requires a factual inquiry that is precluded at this stage.

Defendants next argue that the Complaint must be dismissed because they acted within an objectively reasonable interpretation of the requirements applicable to them. The government again protests, arguing that Defendants deliberately misinterpreted unambiguous legal requirements and ignored repeated warnings that their coding practices were yielding false submissions.

As indicated above, some FCA claims may fail because "a defendant cannot act 'knowingly' if it bases its actions on an objectively reasonable interpretation of the relevant statute[, regulation, or contractual provision] when it has not been warned away from that interpretation by authoritative guidance." United States ex rel. Sheldon, 24 F.4th at 348; see also United States ex rel. Johnson, 223 F. Supp. 3d at 891 ("In short, if a regulation is ambiguous, a defendant may escape liability if its interpretation of the regulation was reasonable in light of available official guidance—even if the interpretation was 'opportunistic.'").

Similar to the conclusions in the preceding section, this Court finds that the reasonableness of Defendants' interpretations cannot be determined at the pleading stage, nor is dismissal appropriate given the government's allegations of deliberate conduct violative of the FCA, which include allegations that Defendants were warned away from their conduct by administrative guidance, third-party audits, internal complaints, and the practices of other health-care organizations (see, e.g., Complaint at

¶¶ 9, 111, 113, 115-118, 123, 124, 294, 314-326, 334, 335, 344, 345, 354, 371-374, 378, 386-412). Consequently, this argument fails.

5. The government sufficiently alleges that IH knew that DxID's coding and addenda policies were unlawful.

Defendants next argue that the government inadequately pleads IH's[8] knowledge that its coding and addenda policies were unlawful under the heightened pleading requirements of Rule 9 (b). The government maintains that its allegations meet the pleading standards.

Under the FCA, knowledge includes actual knowledge, deliberate indifference, or reckless disregard of the falsity, but requires no proof of specific intent to defraud. See 31 U.S.C. § 3729(b)(1)(A). The Second Circuit has found that FCA claims "are subject to the particularity requirement of the Federal Rules of Civil Procedure 9(b). Rule 9(b) permits knowledge to be averred generally, but plaintiffs, including the government, still must plead the factual basis which gives rise to a strong inference of fraudulent intent." Strock, 982 F.3d at 66 (internal quotation marks and citations omitted). This may be established through pleadings that either: (a) "show that defendants had both motive and opportunity to commit fraud, or (b) [allege] facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." Id. (internal quotation marks and citation omitted).

Here, the Complaint adequately avers that IH had knowledge of and had been warned about DxID's practices (see Complaint at ¶ 9 ("IH received ample warning about the impropriety of DxID's coding policies and that DxID's aggressive coding approach

[8] Defendants do not argue that the Complaint inadequately pleads DxID's or Gaffney's knowledge.

would cause submission of unsupported diagnosis codes."); see also id. at ¶¶ 111, 123 (alleging that IH employees recognized problems with Cognisight's practices and DxID implemented the same practices); see also id. at ¶¶ 113, 115-118, 124, 294, 314-326, 334, 335, 344, 345, 354, 371-374, 378, 386-412). Additionally, the government sufficiently alleges that IH possessed motive and opportunity to commit fraud based on the tens of millions of dollars that it received from CMS through submission of diagnosis codes generated by DxID's coding practices (see id. ¶¶ 5, 21, 134, 404, 407). Consequently, this Court concludes that the government has adequately pleaded IH's knowledge consistent with Rule 9 (b).

6. The Complaint fails to state an FCA conspiracy claim.

Defendants argue that dismissal of the government's FCA conspiracy claim is required under the intra-corporate conspiracy doctrine since related entities cannot conspire with each other or their employees. In response, the government disclaims alleging an intra-corporate conspiracy and instead maintains that the Complaint alleges an FCA conspiracy involving Defendants and third parties, such as GHC, Cognisight, and provider groups and doctors. It further contends that an exception to the general rule on intra-corporate conspiracies applies to Gaffney, as an individual who was motivated by an independent personal stake.

"[U]nder the intra-corporate conspiracy doctrine, one entity cannot conspire with its employees" and "it is well established that one corporation and a wholly-owned subsidiary cannot conspire with each other." Pencheng Si v. Laogai Rsch. Found., 71 F. Supp. 3d 73, 98 (D.D.C. 2014).

Here, there is an intra-corporate relationship between IHA, IHC, and DxID, and Gaffney is an employee of DxID (see Complaint at ¶¶ 25-28). While the government seeks to avoid application of the intra-corporate doctrine by arguing that it alleges a conspiracy involving third parties, such as GHC and others, the Complaint fails to provide adequate notice that the referenced third-party interactions form the basis of the conspiracy claim.

Rather, the Complaint's overt conspiracy allegations exclusively involve Defendants' interactions with each other. For example, the government alleges at the outset that Defendants "conspired with the other defendants to violate the FCA" (id at ¶¶ 2, 22).[9] The Complaint further contains a subsection entitled "Defendants Conspired to Commit Fraud," which again identifies the conspirators as "IH, DxID, and Gaffney," with no reference to other entities or individuals (id. at ¶¶ 126-28). And further still, the government identifies only "IHA, IHC, DxID, and Gaffney" as conspirators in its delineated cause of action (id. at ¶ 430), and relies exclusively on payments CMS made only for Defendants' beneficiaries (not for any other MAOs' beneficiaries) (id. at ¶ 431).

The conspiracy claim is also not saved by the government's argument that Gaffney had a personal stake separate from the corporate defendants. Although courts in this circuit recognize an exception to the intra-corporate conspiracy doctrine when a party acts pursuant to personal interests "separate and apart from the entity," the Complaint here contains no such allegations. Vega v. Artus, 610 F. Supp. 2d 185, 205 (N.D.N.Y. 2009) (internal quotation marks and citation omitted); see also Girard v. 94th St. & Fifth Ave. Corp., 530 F.2d 66, 72 (2d Cir. 1976) ("The plaintiff must also allege that they acted other

[9] While GHC was once a defendant in this case, GHC was no longer a defendant when the operative Complaint was filed, and GHC is not listed as a defendant in the caption or body of the Complaint.

than in the normal course of their corporate duties." (internal quotation marks and citation omitted)).

Accordingly, this Court finds that the conspiracy claim must be dismissed without prejudice under the intra-corporate doctrine.

C. Common-Law Claims (Claims 6 and 7)

Defendants seek to dismiss the government's payment-in-mistake and unjust enrichment claims as derivative of their FCA claims and as barred by the contracts between the parties. The government maintains that it is permitted to assert its common law claims against DxID and Gaffney because they were not parties to CMS contracts, and that it is permitted to assert the claims against IH as alternative quasi-contract claims, particularly because Defendants challenge the CMS contract terms.

First, the government's assertions concerning DxID and Gaffney are correct: they are not alleged to have entered CMS contracts.

Second, the government correctly maintains that it can maintain its common-law claims against IH as alternative quasi-contract claims. Although "quasi-contract theories such as payment by mistake and money had and received are generally precluded by the existence of an express contract," Albrecht v. Comm. on Emp. Benefits, 357 F.3d 62, 69 (D.C. Cir. 2004); see also Scott v. Fields, 92 A.D.3d 666, 669 (N.Y. App. Div. 2012), there must be "something in the contract that expressly governs the conduct that is the subject of the inequitable conduct at issue before the existence of the contract will be found to prevent the assertion of quasi-contractual claims for payment by mistake or unjust enrichment for that inequitable conduct," United States v. United Techs. Corp., No. 3:99-CV-093, 2012 WL 2263280, at *5 (S.D. Ohio June 18, 2012); see also Port Auth. of N.Y.

& N.J. v. Brooklyn Union Gas Co., 179 A.D.3d 1106, 1109 (N.Y. App. Div. 2020) ("The existence of a valid and enforceable written contract governing *a particular subject matter* precludes recovery in quasi contract *for events arising out of the same subject matter*." (emphasis added) (internal quotation marks and citation omitted)).

Here, the parties dispute whether all of the alleged conduct was governed by the CMS contracts. More specifically, the parties dispute whether the contract required, or could require, Defendants to comply with agency guidance (see Memorandum of Law, Docket No. 156, p. 21 (arguing that pursuant to the contract, Defendants agreed to and were contractually bound to comply with CMS policies and guidance); Memorandum of Law, Docket No. 157, p. 11 (arguing that: (1) any requirement in the contract requiring compliance with agency guidance conflicted with the Medicare Act's requirement that substantive legal rules be promulgated through notice-and-comment rulemaking, and (2) the language requiring compliance with CMS policies is irrelevant because it appears in the portion of the contract addressing plan design and not payment)).

Accordingly, given the broad pleading standards allowing alternative theories of recovery, this Court finds it appropriate to allow the government's common-law claims to proceed at this stage.

D. Leave to Amend

The government requests leave to amend any claim found subject to dismissal, which Defendants oppose. Given that district courts have broad discretion to grant a party leave to amend its pleadings and the federal rules dictate that courts "freely give leave when justice so requires" Fed. R. Civ. P. 15 (a)(2); see also Foman v. Davis, 371 U.S. 178, 182, 83 S. Ct. 227, 230, 9 L. Ed. 2d 222 (1962); Ellis v. Chao, 336 F.3d 114,

127 (2d Cir. 2003), this Court will grant the government leave to amend its conspiracy claim, which is the only claim found subject to dismissal.

IV. CONCLUSION

For the reasons stated above, this Court finds that the government's Complaint adequately alleges FCA and common-law claims, but fails to plead an FCA conspiracy claim. Defendants' motion to dismiss will therefore be denied in part and granted in part, and the government will be granted leave to amend its conspiracy claim.

V. ORDERS

IT HEREBY IS ORDERED, that Defendants' Motion to Dismiss (Docket No. 154) is DENIED IN PART and GRANTED IN PART.

FURTHER, that the government is GRANTED leave to amend its conspiracy claim through the filing of a First Amended Complaint-in-Intervention.

FURTHER, that the government must file its First Amended Complaint-in-Intervention within 14 days of the entry date of this decision.

SO ORDERED.

Dated: January 3, 2023
Buffalo, New York

s/William M. Skretny
WILLIAM M. SKRETNY
United States District Judge